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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/799,264

03/12/2004

Don Fishbein

52427-AA/JPW/GJG

8229

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EXAMINER

HUGHES, ALICIA R

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

10/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	<p>Application No. 10/799,264</p>	<p>Applicant(s) FISHBEIN, DON</p>	
	<p>Examiner ALICIA R. HUGHES</p>	<p>Art Unit 1614</p>	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 April 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 03 April 2009. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 30-47.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

/KEVIN WEDDINGTON/
Primary Examiner, Art Unit 1614

Continuation of 11. does NOT place the application in condition for allowance because: With regard to the first 103(a) rejection, claims 30-40 and 42-47 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,090,799 [hereinafter referred to as "Berger"] in view of U.S. Patent No. 4,456,596 [hereinafter referred to as "Schaffer"]. Applicant continues to argue that a prima facie case of obviousness has not been established over claims 30-47 because the references used and the claimed invention are directed to different patient populations, weight loss etiologies for these populations are not the same, and the differing etiologies are of consequence and therefore, there is no demonstrable reasonable expectation of success.. More specifically, Applicant argues that Schaffer does not explicitly state that anabolic steroids are used systemically to treat burns, but rather, refers to medicinal literature and that Berger and Schaffer are not combinable, because the technical fields of the two references differ. The Applicant also continues to argue that there are unexpected results.

The first 103(a) rejection is maintained nevertheless for the reasons already made of record.

With regard to the second 103(a) rejection, Claims 30 and 41 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,090,799 [hereinafter referred to as "Berger"] in view of U.S. Patent No. 4,456,596 [hereinafter referred to as "Schaffer"] and in further view of U.S. Patent No. 5,434,146 [hereinafter referred to as "Labrie et al"].

The Applicant continues to argue that this rejection fails to stand based on the alleged deficiencies of Berger as noted supra. The arguments in response thereto as noted in the first 103(a) rejection, supra, are incorporated herein by reference in their entirety. And as noted prior, while Berger does not teach the administration of oxandrolone in a sustained release formulation, Labrie et al teach the administration of certain anabolic steroids, including oxandrolone, in a sustained release formulation. For the reasons already made of record, one of ordinary skill in the art would have been motivated to combine these references at the time the instant invention was contemplated to arrive at the instant invention. As a result, this rejection, too, stands.